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Re-evaluation Decision RVD2018-19

Trichoderma harzianum Rifai strain KRL-AG2 and Its Associated End-use Products

Final Decision

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Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Trichoderma harzianum Rifai strain KRL-AG2 is a biological fungicide registered for the suppression of root and foliar diseases on greenhouse crops, outdoor nursery plants and agricultural field crops. It can be applied as a soil drench, bulb dip, seed treatment, and as a ground foliar spray. Currently registered products containing *Trichoderma harzianum* Rifai strain KRL-AG2 are listed in Appendix I.

This document presents the final regulatory decision[1] for the re-evaluation of *Trichoderma harzianum* Rifai strain KRL-AG2. All pest control products containing *Trichoderma harzianum* Rifai strain KRL-AG2 that are registered in Canada are subject to this re-evaluation decision. This re-evaluation decision has undergone a 90-day consultation period as the Proposed Re-evaluation Decision PRVD2017-20, *Trichoderma harzianum Rifai strain KRL-AG2 and Its Associated End-use Products*[2].

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2017-20, which lists all data used as the basis for the re-evaluation decision.

Regulatory Decision for *Trichoderma harzianum* Rifai strain KRL-AG2

The PMRA has completed the re-evaluation *Trichoderma harzianum* Rifai strain KRL-AG2. Under the authority of the *Pest Control Products Act*, the PMRA is granting continued registration of products containing *Trichoderma harzianum* Rifai strain KRL-AG2 for sale and use in Canada. An evaluation of available scientific information found that uses of *Trichoderma harzianum* Rifai strain KRL-AG2 products do not present unacceptable risks to human health or environment when used according to the conditions of registration, including amended label directions. Label amendments, as summarized below and listed in Appendix II, are required for all end-use products. No additional data are requested at this time.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

2 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Risk Mitigation Measures

Registered pesticide product labels include specific direction for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law.

The following label amendments are included as part of the re-evaluation.

Health

- Restricted-entry intervals

Environment

- Precautionary label statement to minimize the potential for spray drift
- Environmental label statements

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all products labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing *Trichoderma harzianum* Rifai strain KRL-AG2 that are registered under the authority of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[3] regarding this decision on *Trichoderma harzianum* Rifai strain KRL-AG2 within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Registered *Trichoderma harzianum* Rifai strain KRL-AG2 Products in Canada

Table 1 Registered *Trichoderma harzianum* Rifai strain KRL-AG2 Products in Canada[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
31054	M	Bioworks Inc	Rootshield® plus granules biological fungicide	Granular	TDG: 5.3×10^6 FTR: 1×10^7
27115	C	Bioworks Inc	Rootshield HC biological fungicide wettable powder	Live Organism	FTR: 1×10^7
27116	C	Bioworks Inc	Rootshield granules biological fungicide	Live Organism	FTR: 1×10^7
29890	C	Bioworks Inc	Rootshield® WP - biological fungicide	Live Organism	FTR: 1×10^7
30539	C	Bioworks Inc	Rootshield® plus WP biological fungicide	Live Organism	TDG: 5.3×10^6 FTR: 1×10^7
31989	C	Bioworks Inc	BW240 WP biological fungicide	Live Organism	TDG: 5.3×10^6 FTR: 1×10^7
27114	T	Bioworks Inc	Rootshield technical biological fungicide	Live Organism	FTR: 5×10^8
31103	C	AEF Global Inc	Bora HC	Live Organism	FTR: 1×10^7
31104	C	AEF Global Inc	Bora WP (Wettable Powder)	Live Organism	FTR: 1×10^7

[1] as of 4 April 2018, excluding discontinued products or products with a submission for discontinuation

Appendix II Label Amendments for Products Containing *Trichoderma harzianum Rafai* strain KRL-AG2

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following label statements are required:

I) The following statement must be included under the **RE-ENTRY INTERVAL section for end-use products with indoor and outdoor foliar applications** (excluding granular formulations):

- "DO NOT re-enter or allow re-entry into treated areas for 4 hours or until sprays have dried, unless wearing appropriate personal protective equipment including long-sleeved shirt, long pants, shoes plus socks, and waterproof gloves."

II) The following statement must be included under the **PRECAUTIONS section for all end-use product labels with outdoor uses**:

- "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

III) The following statements must be included under the **ENVIRONMENTAL PRECAUTIONS section for all end-use products**:

- "To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay."
- "Avoid application when heavy rain is forecast."
- "Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

IV) The following statements must be included under the **DIRECTIONS FOR USE section for all end-use products**:

- "DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

V) The following statement must be included under the **DIRECTIONS FOR USE section for all end-use products with greenhouse uses:**

> "DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters."